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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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AGILENT TECHNOLOGIES, INC.
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

EXAMINER

MARIAM, DANIEL G

ART UNIT PAPER NUMBER

2621

DATE MAILED: 07/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/895,756

Applicant(s)

CONNELL ET AL.

Examiner

DANIEL G MARIAM

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,8-16,19,20 and 22 is/are rejected.
- 7) ☒ Claim(s) 3,4,7,17,18 and 21 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6 & 7</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claims 5- 6 and 19-20 are objected to because of the following informalities: claim 5 contains two periods, and claim 19 also contains two periods. Each claim should begin with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations (See MPEP 608.01(M)). Appropriate correction is required
2. Since claims 6 and 20 depend on claims 5 and 19 respectively, they are also objected to for the same reason set forth above for claims 5 and 19.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "chi-squared and chi0squared" in lines 2 and 4. It is unclear what chi-squared and chi0squared suppose to mean. Please clarify.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 9, 11-13, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Chu, et al. (6,249,593).

With regard to claim 1, Chu, et al. discloses a method for identifying a non-uniform, i.e., error and/or background noise, measured signal distribution in a region of a scanned image of a molecular array (See for example, Figure 1), the method comprising: providing a variance model, i.e., mathematical function, for measured signal distributions within regions of the molecular array, determining a variance, i.e., difference obtained by subtracting the background density from the analyte density, of measured signals within the region, and determining whether or not the region contains a non-uniform measured signal distribution by comparing the determined variance of measured signals within the region to the variance model (See for example, col. 4, lines 1-40; and col. 9, lines 11-56).

With regard to claim 9, the method of claim 1 wherein the region is selected from among a feature, i.e., analyte, and a feature background (See for example, col. 9, lines 40-56).

With regard to claim 11, a representation of a non-uniform measured signal distribution in a region of a scanned image of a molecular array identified by the method of claim 1 stored in a computer-readable medium (See Figure 1).

With regard to claim 12, results produced by a molecular array data processing program employing the method of claim 1 stored in a computer-readable medium (See Figure 1).

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With regard to claim 13, results produced by a molecular array data processing program employing the method of claim 1 transferred to an intercommunicating entity via electronic signals (See Figure 1).

Claim 15 is rejected the same as claim 1 except claim 15 is directed to a method claim. Thus, argument analogous to that presented above for claim 1 is equally applicable to claim 15. As to the computational processing engine, applicants' attention is invited to item 104, in Figure 1.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-2, 10, 13-16, and 22 rejected under 35 U.S.C. 103(a) as being unpatentable over Fitzgerald, et al. (6,341,182).

With regard to claim 1, Fitzgerald, et al. discloses a method for identifying a non-uniform measured signal distribution in a region, i.e., pixel value that lie outside of a region of interest, absence of analyte, or non-analyte signals, of a scanned image of a molecular array (See for example, Abstract; and Fig. 1), the method comprising: providing a variance model for measured signal distributions within regions of the molecular array (See for example, col. 1, lines 33-44), determining a variance of measured signals within the region, and determining whether or not the region contains a non-uniform measured signal distribution by comparing the determined

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variance of measured signals within the region to the variance model (See for example, col. 2, line 61 – col. 3, line 23). Although Fitzgerald, et al. does not explicitly provide a variance model within regions of the molecular array, it would have been an obvious matter of design choice to modify the statistical analysis as taught by Fitzgerald, et al. (See col. 1, lines 36-44) by replacing it with the variance model to determine the presence or absence of the analyte signals within the regions/sites, since no new or unexpected results are seen to be attained by providing a variance model, the statistical analysis can be used for determining the absence of the analyte in the regions/sites.

With regard to claim 2, the method of claim 1 further including determining a variance threshold from the variance model, and wherein comparing the determined variance of measured signals within the region to the variance model comprises comparing the determined variance of measured signals within the region to the determined variance threshold (which reads on col. 9, lines 41-51).

With regard to claim 10, the method of claim 1 wherein the variance model is provided according to chemical and physical properties of the molecular array, electronic and physical properties of a scanning device, and experimental conditions to which the molecular array is exposed (See Figure 1).

With regard to claim 13, results produced by a molecular array data processing program employing the method of claim 1 transferred to an intercommunicating entity via electronic signals (See for example, Figure 1).

With regard to claim 14, results produced by a molecular array data processing program employing the method of claim 1 printed in a human-readable format (See item 7, in Fig. 1).

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Claim 15 is rejected the same as claim 1 except claim 15 is directed to a method claim.

Thus, argument analogous to that presented above for claim 1 is equally applicable to claim 15.

Claim 16 is rejected the same as claim 2 except claim 16 is directed to a method claim.

Thus, argument analogous to that presented above for claim 2 is equally applicable to claim 16.

Claim 22 is rejected the same as claim 10 except claim 22 is directed to a method claim.

Thus, argument analogous to that presented above for claim 10 is equally applicable to claim 22.

Allowable Subject Matter

9. Claims 3, 4, 7, 17-18, and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. None of the prior art of record teach or fairly suggest wherein: the scanned image comprises pixels, each pixel associated with a count representing a signal measured from a corresponding portion of the molecular array, the variance model is a linear combination of model variance terms, and the variance model is an expression including a mean pixel count for the region as a variable. It is for this reason that claims 3, 4, 7, 17-18, and 21 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent Numbers: 5837475, 6083763, 6100030, 6349144, and 6516276.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL G MARIAM whose telephone number is 703-305-4010. The examiner can normally be reached on M-F (7:00-4:30) FIRST FRIDAY OFF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LEO BOUDREAU can be reached on 703-305-4607. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


DANIEL MIRIAM
PRIMARY EXAMINER

July 22, 2004